

care services) to Medicaid beneficiaries; or

(2) A PCCM entity contracts with the State to provide a defined set of functions.

*Primary care case management entity (PCCM entity)* means an organization that provides any of the following functions, in addition to primary care case management services, for the State:

(1) Provision of intensive telephonic or face-to-face case management, including operation of a nurse triage advice line.

(2) Development of enrollee care plans.

(3) Execution of contracts with and/or oversight responsibilities for the activities of FFS providers in the FFS program.

(4) Provision of payments to FFS providers on behalf of the State.

(5) Provision of enrollee outreach and education activities.

(6) Operation of a customer service call center.

(7) Review of provider claims, utilization and practice patterns to conduct provider profiling and/or practice improvement.

(8) Implementation of quality improvement activities including administering enrollee satisfaction surveys or collecting data necessary for performance measurement of providers.

(9) Coordination with behavioral health systems/providers.

(10) Coordination with long-term services and supports systems/providers.

*Primary care case manager (PCCM)* means a physician, a physician group practice or, at State option, any of the following:

(1) A physician assistant.

(2) A nurse practitioner.

(3) A certified nurse-midwife.

*Provider* means any individual or entity that is engaged in the delivery of services, or ordering or referring for those services, and is legally authorized to do so by the State in which it delivers the services.

*Rate cell* means a set of mutually exclusive categories of enrollees that is defined by one or more characteristics for the purpose of determining the capitation rate and making a capitation payment; such characteristics

may include age, gender, eligibility category, and region or geographic area. Each enrollee should be categorized in one of the rate cells for each unique set of mutually exclusive benefits under the contract.

*Rating period* means a period of 12 months selected by the State for which the actuarially sound capitation rates are developed and documented in the rate certification submitted to CMS as required by § 438.7(a).

*Risk contract* means a contract between the State and an MCO, PIHP or PAHP under which the contractor—

(1) Assumes risk for the cost of the services covered under the contract; and

(2) Incurs loss if the cost of furnishing the services exceeds the payments under the contract.

*State* means the Single State agency as specified in § 431.10 of this chapter.

*Subcontractor* means an individual or entity that has a contract with an MCO, PIHP, PAHP, or PCCM entity that relates directly or indirectly to the performance of the MCO's, PIHP's, PAHP's, or PCCM entity's obligations under its contract with the State. A network provider is not a subcontractor by virtue of the network provider agreement with the MCO, PIHP, or PAHP.

### § 438.3 Standard contract requirements.

(a) *CMS review.* The CMS must review and approve all MCO, PIHP, and PAHP contracts, including those risk and nonrisk contracts that, on the basis of their value, are not subject to the prior approval requirement in § 438.806. Proposed final contracts must be submitted in the form and manner established by CMS. For States seeking approval of contracts prior to a specific effective date, proposed final contracts must be submitted to CMS for review no later than 90 days prior to the effective date of the contract.

(b) *Entities eligible for comprehensive risk contracts.* A State may enter into a comprehensive risk contract only with the following:

(1) An MCO.

(2) The entities identified in section 1903(m)(2)(B)(i), (ii), and (iii) of the Act.

(3) Community, Migrant, and Appalachian Health Centers identified in section 1903(m)(2)(G) of the Act. Unless they qualify for a total exemption under section 1903(m)(2)(B) of the Act, these entities are subject to the regulations governing MCOs under this part.

(4) An HIO that arranges for services and became operational before January 1986.

(5) An HIO described in section 9517(c)(3) of the Omnibus Budget Reconciliation Act of 1985 (as amended by section 4734(2) of the Omnibus Budget Reconciliation Act of 1990).

(c) *Payment.* The following requirements apply to the final capitation rate and the receipt of capitation payments under the contract:

(1) The final capitation rate for each MCO, PIHP or PAHP must be:

(i) Specifically identified in the applicable contract submitted for CMS review and approval.

(ii) The final capitation rates must be based only upon services covered under the State plan and additional services deemed by the State to be necessary to comply with the requirements of subpart K of this part (applying parity standards from the Mental Health Parity and Addiction Equity Act), and represent a payment amount that is adequate to allow the MCO, PIHP or PAHP to efficiently deliver covered services to Medicaid-eligible individuals in a manner compliant with contractual requirements.

(2) Capitation payments may only be made by the State and retained by the MCO, PIHP or PAHP for Medicaid-eligible enrollees.

(d) *Enrollment discrimination prohibited.* Contracts with MCOs, PIHPs, PAHPs, PCCMs and PCCM entities must provide as follows:

(1) The MCO, PIHP, PAHP, PCCM or PCCM entity accepts individuals eligible for enrollment in the order in which they apply without restriction (unless authorized by CMS), up to the limits set under the contract.

(2) Enrollment is voluntary, except in the case of mandatory enrollment programs that meet the conditions set forth in § 438.50(a).

(3) The MCO, PIHP, PAHP, PCCM or PCCM entity will not, on the basis of health status or need for health care

services, discriminate against individuals eligible to enroll.

(4) The MCO, PIHP, PAHP, PCCM or PCCM entity will not discriminate against individuals eligible to enroll on the basis of race, color, national origin, sex, or disability and will not use any policy or practice that has the effect of discriminating on the basis of race, color, or national origin, sex, or disability.

(e) *Services that may be covered by an MCO, PIHP, or PAHP.* (1) An MCO, PIHP, or PAHP may cover, for enrollees, services that are in addition to those covered under the State plan as follows:

(i) Any services that the MCO, PIHP or PAHP voluntarily agree to provide, although the cost of these services cannot be included when determining the payment rates under paragraph (c) of this section.

(ii) Any services necessary for compliance by the MCO, PIHP, or PAHP with the requirements of subpart K of this part and only to the extent such services are necessary for the MCO, PIHP, or PAHP to comply with § 438.910.

(2) An MCO, PIHP, or PAHP may cover, for enrollees, services or settings that are in lieu of services or settings covered under the State plan as follows:

(i) The State determines that the alternative service or setting is a medically appropriate and cost effective substitute for the covered service or setting under the State plan;

(ii) The enrollee is not required by the MCO, PIHP, or PAHP to use the alternative service or setting;

(iii) The approved in lieu of services are authorized and identified in the MCO, PIHP, or PAHP contract, and will be offered to enrollees at the option of the MCO, PIHP, or PAHP; and

(iv) The utilization and actual cost of in lieu of services is taken into account in developing the component of the capitation rates that represents the covered State plan services, unless a statute or regulation explicitly requires otherwise.

(f) *Compliance with applicable laws and conflict of interest safeguards.* All contracts with MCOs, PIHPs, PAHPs, PCCMs and PCCM entities must:

(1) Comply with all applicable Federal and State laws and regulations including Title VI of the Civil Rights Act of 1964; Title IX of the Education Amendments of 1972 (regarding education programs and activities); the Age Discrimination Act of 1975; the Rehabilitation Act of 1973; the Americans with Disabilities Act of 1990 as amended; and section 1557 of the Patient Protection and Affordable Care Act.

(2) Comply with the conflict of interest safeguards described in § 438.58 and with the prohibitions described in section 1902(a)(4)(C) of the Act applicable to contracting officers, employees, or independent contractors.

(g) *Provider-preventable condition requirements.* All contracts with MCOs, PIHPs and PAHPs must comply with the requirements mandating provider identification of provider-preventable conditions as a condition of payment, as well as the prohibition against payment for provider-preventable conditions as set forth in § 434.6(a)(12) and § 447.26 of this chapter. MCOs, PIHPs, and PAHPs, must report all identified provider-preventable conditions in a form and frequency as specified by the State.

(h) *Inspection and audit of records and access to facilities.* All contracts must provide that the State, CMS, the Office of the Inspector General, the Comptroller General, and their designees may, at any time, inspect and audit any records or documents of the MCO, PIHP, PAHP, PCCM or PCCM entity, or its subcontractors, and may, at any time, inspect the premises, physical facilities, and equipment where Medicaid-related activities or work is conducted. The right to audit under this section exists for 10 years from the final date of the contract period or from the date of completion of any audit, whichever is later.

(i) *Physician incentive plans.* (1) MCO, PIHP, and PAHP contracts must provide for compliance with the requirements set forth in §§ 422.208 and 422.210 of this chapter.

(2) In applying the provisions of §§ 422.208 and 422.210 of this chapter, references to “MA organization,” “CMS,” and “Medicare beneficiaries” must be read as references to “MCO, PIHP, or

PAHP,” “State,” and “Medicaid beneficiaries,” respectively.

(j) *Advance directives.* (1) All MCO and PIHP contracts must provide for compliance with the requirements of § 422.128 of this chapter for maintaining written policies and procedures for advance directives, as if such regulation applied directly to MCOs and PIHPs.

(2) All PAHP contracts must provide for compliance with the requirements of § 422.128 of this chapter for maintaining written policies and procedures for advance directives as if such regulation applied directly to PAHPs if the PAHP includes, in its network, any of those providers listed in § 489.102(a) of this chapter.

(3) The MCO, PIHP, or PAHP subject to the requirements of this paragraph (j) must provide adult enrollees with written information on advance directives policies, and include a description of applicable State law.

(4) The information must reflect changes in State law as soon as possible, but no later than 90 days after the effective date of the change.

(k) *Subcontracts.* All subcontracts must fulfill the requirements of this part for the service or activity delegated under the subcontract in accordance with § 438.230.

(l) *Choice of network provider.* The contract must allow each enrollee to choose his or her network provider to the extent possible and appropriate.

(m) *Audited financial reports.* The contract must require MCOs, PIHPs, and PAHPs to submit audited financial reports specific to the Medicaid contract on an annual basis. The audit must be conducted in accordance with generally accepted accounting principles and generally accepted auditing standards.

(n) *Parity in mental health and substance use disorder benefits.* (1) All MCO contracts, and any PIHP and PAHP contracts providing services to MCO enrollees, must provide for services to be delivered in compliance with the requirements of subpart K of this part insofar as those requirements are applicable.

(2) Any State providing any services to MCO enrollees using a delivery system other than the MCO delivery system must provide documentation of

how the requirements of subpart K of this part are met with the submission of the MCO contract for review and approval under paragraph (a) of this section.

(o) *LTSS contract requirements.* Any contract with an MCO, PIHP or PAHP that includes LTSS as a covered benefit must require that any services covered under the contract that could be authorized through a waiver under section 1915(c) of the Act or a State plan amendment authorized through sections 1915(i) or 1915(k) of the Act be delivered in settings consistent with § 441.301(c)(4) of this chapter.

(p) *Special rules for certain HIOs.* Contracts with HIOs that began operating on or after January 1, 1986, and that the statute does not explicitly exempt from requirements in section 1903(m) of the Act, are subject to all the requirements of this part that apply to MCOs and contracts with MCOs. These HIOs may enter into comprehensive risk contracts only if they meet the criteria of paragraph (b) of this section.

(q) *Additional rules for contracts with PCCMs.* A PCCM contract must meet the following requirements:

(1) Provide for reasonable and adequate hours of operation, including 24-hour availability of information, referral, and treatment for emergency medical conditions.

(2) Restrict enrollment to beneficiaries who reside sufficiently near one of the PCCM's delivery sites to reach that site within a reasonable time using available and affordable modes of transportation.

(3) Provide for arrangements with, or referrals to, sufficient numbers of physicians and other practitioners to ensure that services under the contract can be furnished to enrollees promptly and without compromise to quality of care.

(4) Prohibit discrimination in enrollment, disenrollment, and re-enrollment, based on the beneficiary's health status or need for health care services.

(5) Provide that enrollees have the right to disenroll in accordance with § 438.56(c).

(r) *Additional rules for contracts with PCCM entities.* In addition to the requirements in paragraph (q) of this section, States must submit PCCM entity

contracts to CMS for review and approval to ensure compliance with the provisions of this paragraph (r); § 438.10; and § 438.310(c)(2).

(s) *Requirements for MCOs, PIHPs, or PAHPs that provide covered outpatient drugs.* Contracts that obligate MCOs, PIHPs or PAHPs to provide coverage of covered outpatient drugs must include the following requirements:

(1) The MCO, PIHP or PAHP provides coverage of covered outpatient drugs as defined in section 1927(k)(2) of the Act, that meets the standards for such coverage imposed by section 1927 of the Act as if such standards applied directly to the MCO, PIHP, or PAHP.

(2) The MCO, PIHP, or PAHP reports drug utilization data that is necessary for States to bill manufacturers for rebates in accordance with section 1927(b)(1)(A) of the Act no later than 45 calendar days after the end of each quarterly rebate period. Such utilization information must include, at a minimum, information on the total number of units of each dosage form, strength, and package size by National Drug Code of each covered outpatient drug dispensed or covered by the MCO, PIHP, or PAHP.

(3) The MCO, PIHP or PAHP establishes procedures to exclude utilization data for covered outpatient drugs that are subject to discounts under the 340B drug pricing program from the reports required under paragraph (s)(2) of this section when states do not require submission of managed care drug claims data from covered entities directly.

(4) The MCO, PIHP or PAHP must operate a drug utilization review program that complies with the requirements described in section 1927(g) of the Act and 42 CFR part 456, subpart K, as if such requirement applied to the MCO, PIHP, or PAHP instead of the State.

(5) The MCO, PIHP or PAHP must provide a detailed description of its drug utilization review program activities to the State on an annual basis.

(6) The MCO, PIHP or PAHP must conduct a prior authorization program that complies with the requirements of section 1927(d)(5) of the Act, as if such requirements applied to the MCO, PIHP, or PAHP instead of the State.

(t) *Requirements for MCOs, PIHPs, or PAHPs responsible for coordinating benefits for dually eligible individuals.* In a State that enters into a Coordination of Benefits Agreement with Medicare for FFS, an MCO, PIHP, or PAHP contract that includes responsibility for coordination of benefits for individuals dually eligible for Medicaid and Medicare must require the MCO, PIHP, or PAHP to enter into a Coordination of Benefits Agreement with Medicare and participate in the automated claims crossover process.

(u) *Recordkeeping requirements.* MCOs, PIHPs, and PAHPs must retain, and require subcontractors to retain, as applicable, the following information: enrollee grievance and appeal records in § 438.416, base data in § 438.5(c), MLR reports in § 438.8(k), and the data, information, and documentation specified in §§ 438.604, 438.606, 438.608, and 438.610 for a period of no less than 10 years.

(v) *Applicability date.* Sections 438.3(h) and (q) apply to the rating period for contracts with MCOs, PIHPs, PAHPs, PCCMs, and PCCM entities beginning on or after July 1, 2017. Until that applicability date, states are required to continue to comply with § 438.6(g) and (k) contained in the 42 CFR, parts 430 to 481, edition revised as of October 1, 2015.

[81 FR 27853, May 6, 2016, as amended at 85 FR 37243, June 19, 2020]

#### § 438.4 Actuarial soundness.

(a) *Actuarially sound capitation rates defined.* Actuarially sound capitation rates are projected to provide for all reasonable, appropriate, and attainable costs that are required under the terms of the contract and for the operation of the MCO, PIHP, or PAHP for the time period and the population covered under the terms of the contract, and such capitation rates are developed in accordance with the requirements in paragraph (b) of this section.

(b) *CMS review and approval of actuarially sound capitation rates.* Capitation rates for MCOs, PIHPs, and PAHPs must be reviewed and approved by CMS as actuarially sound. To be approved by CMS, capitation rates must:

(1) Have been developed in accordance with standards specified in § 438.5 and generally accepted actuarial prin-

ciples and practices. Any proposed differences among capitation rates according to covered populations must be based on valid rate development standards and not based on the rate of Federal financial participation associated with the covered populations.

(2) Be appropriate for the populations to be covered and the services to be furnished under the contract.

(3) Be adequate to meet the requirements on MCOs, PIHPs, and PAHPs in §§ 438.206, 438.207, and 438.208.

(4) Be specific to payments for each rate cell under the contract.

(5) Payments from any rate cell must not cross-subsidize or be cross-subsidized by payments for any other rate cell.

(6) Be certified by an actuary as meeting the applicable requirements of this part, including that the rates have been developed in accordance with the requirements specified in § 438.3(c)(1)(ii) and (e).

(7) Meet any applicable special contract provisions as specified in § 438.6.

(8) Be provided to CMS in a format and within a timeframe that meets requirements in § 438.7.

(9) Be developed in such a way that the MCO, PIHP, or PAHP would reasonably achieve a medical loss ratio standard, as calculated under § 438.8, of at least 85 percent for the rate year. The capitation rates may be developed in such a way that the MCO, PIHP, or PAHP would reasonably achieve a medical loss ratio standard greater than 85 percent, as calculated under § 438.8, as long as the capitation rates are adequate for reasonable, appropriate, and attainable non-benefit costs.

#### § 438.5 Rate development standards.

(a) *Definitions.* As used in this section and § 438.7(b), the following terms have the indicated meanings:

*Budget neutral* means a standard for any risk sharing mechanism that recognizes both higher and lower expected costs among contracted MCOs, PIHPs, or PAHPs under a managed care program and does not create a net aggregate gain or loss across all payments under that managed care program.

*Prospective risk adjustment* means a methodology to account for anticipated variation in risk levels among